TAB 1

510(K) SUMMARY OF SAFETY & EFFECTIVENESS

FEB - 9 2001

Official Contact

David J. Vanella
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Respironics, Inc.
1001 Murry Ridge Lane
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Classification Reference [none designated]

Product Code 84 LEL

Common/Usual Name Sleep Assessment Device

Proprietary Name REMview Sleep Recorder

Predicate Device Somnitor 32K Activity Monitor (K965079)
HMS-5000 Physiological Monitor (K914085)

Reason for submission New Device

Substantial Equivalence

The REMview device has the following key similarities to the predicate devices:

- Intended use.
- Environment of use.
- Operating principle.
- Technology.

Respironics has determined that the differences from the predicate devices have no impact on the safety and effectiveness of the device. Design verification tests were performed on the REMview Sleep Recorder as a result of the risk analysis and product requirements. All tests were verified to

meet the required acceptance criteria. In summary, the device described in this submission is substantially equivalent to the predicate devices.

The device complies with the applicable standards referenced in the Guidance for FDA Reviewers and Industry "Guidance for the Content of premarket Submissions for Software Contained in Medical Devices," May 1998.

Intended Use

The REMview Sleep Recorder is intended to record patient and eyelid movement for the evaluation of waking and sleeping states. The data can be transferred to a personal computer to determine the periods when the patient was awake or asleep, and to distinguish REM sleep from nonREM sleep. It is intended for use in the home or institutional setting on patients weighing $\geq$ 30 kg.

Device Description

The REMview is designed as a tool to evaluate sleep. REMview consists of a recorder and host software. Key features include:

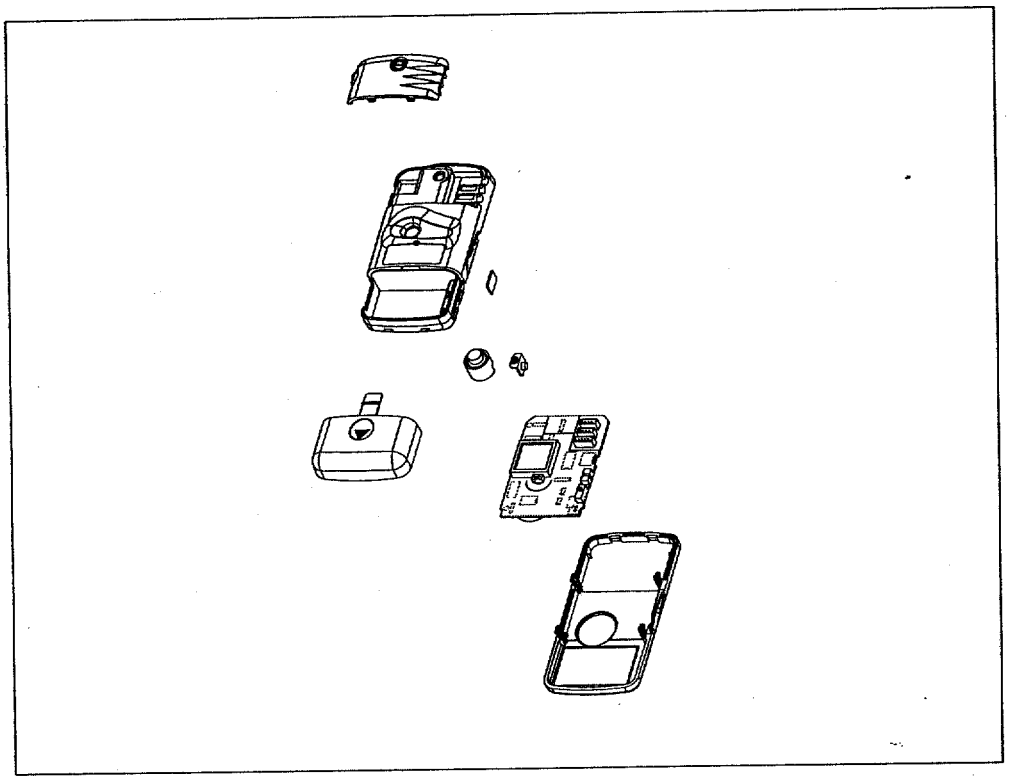
- The recorder is a battery-powered unit that interfaces with predefined sensors, a head motion sensor and an eyelid sensor. The recorder also has a patient event button to enable feedback from the patient.
- The recorder has a serial interface that connects to a host computer for the purpose of either transferring data from the recorder at a time after acquisition or transmitting data to the host computer periodically as it is acquired.
- The host software application receives, stores and displays the data. The program also differentiates wake, REM sleep (rapid eye movement sleep) and nonREM sleep. The software calculates various statistics to help the professional quantify various aspects of the patient's sleep. The software also has the ability to generate and print reports.
- The recorder has an isolation adapter module to provide electrical isolation between the recorder and the host computer.

-- Continued on the next page. --

Functional Description

The REMview product consists of a recorder that measures 11.5cm x 5.8cm x 2 cm in dimension. The following exploded-view drawing depicts the REMview recorder. The recorder operates on a 9-volt DC battery as specified in the operator's manual. The battery compartment of the REMview measures 5cm x 3 cm x 1.8 cm. The REMview can simultaneously record 3 different parameters:

- Eyelid movement count
- Head movement count
- Occurrence of patient event button depression



(End of Section.)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 9 2001

Mr. David J. Vanella
Manager, Regulatory/Product Assurance
Respironics
1001 Murry Ridge Lane
Murrysville, Pennsylvania 15668-8550

Re: K003499
Trade Name: Respironics® REMview Sleep Recorder
Regulatory Class: II
Product Code: LEL
Dated: November 13, 2000
Received: November 13, 2000

Dear Mr. Vanella:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K003499

Device Name: Respironics® REMview Sleep Recorder

Intended Use/Indications for Use

The REMview Sleep Recorder is intended to record patient and eyelid movement for the evaluation of waking and sleeping states. The data can be transferred to a personal computer to determine the periods when the patient was awake or asleep, and to distinguish REM sleep from nonREM sleep.

Environment of Use/Patient Population

Home or Institutional Setting – Intended for patients weighing ≥ 30 kg.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use

(Per 21 CFR 801.109) (Optional Format 1-2-96)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K003499